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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,353	05/02/1997	YESOOK KIM	PC9563JTJ	4835

23913 7590 10/12/2006

PFIZER INC
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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 08/850,353	Applicant(s) KIM, YESOOK	
	Examiner Everett White	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2006 has been entered.

2. The amendment filed August 23, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claims 1, 2 and 4-15 previously canceled;
- (B) Claims 17 and 18 have been added;
- (C) Claims 3 and 16 have been amended;
- (D) Comments regarding Office Action have been provided drawn to:
 - (I) 102(a) rejection, which has been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. Claims 3 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiesi et al (US Patent No. 5,773,029) in view of Matsumura et al (JP Publication No. 03072425 A).

Applicant claims a method of determining a useful salt, from within a series of salts of a particular medicinal compound, for use in making a composition of matter comprising an inclusion complex of said salt in a cyclodextrin, said method comprising: (a) determining a quantity of said medicinal compound required for therapeutic efficacy; (b) choosing a maximum total dose in which to administer said quantity of medicinal compound; (c) calculating the minimum required solubility of a salt of said compound necessary to formulate said maximum total dose; (d) obtaining said series of salts; (e) determining the equilibrium solubility of each of said salts in said cyclodextrin; and (f) selecting, as said useful salt, a salt from said series having an equilibrium solubility in said cyclodextrin sufficient to permit making a total dose equal to or less than said maximum total dose; wherein said medicinal compound is ziprasidone.

The Chiesi et al patent recites the solubility of different compounds and salts thereof under various conditions, at equilibrium, that can be compared in order to select a desired compound or salt. The Chiesi et al patent discloses multicomponent inclusion complexes wherein a multicomponent inclusion complex comprises an acidic drug, a base and a cyclodextrin, wherein a complex is obtained by simultaneous salt formation and complexation. See column 2, lines 54-61 for examples of cyclodextrin derivatives that can be used in the preparation of the inclusion complexes which include alpha and gamma CD, hydroxypropyl- β CD (HPBCD), dimethyl- β CD (DIMEB), random methylated - β -cyclodextrin (RAMED) and other cyclodextrin derivatives. In the next 2 paragraphs in this column Chiesi et al discloses that the basic component of the complexes according to the invention can be of both inorganic and organic nature, which specific examples include alkali or alkaline earth hydroxides, secondary or tertiary amines, such as diethanolamine, triethanolamine, diethylamine, methylamine, trimethamine (TRIS) and the like. In the first two paragraphs in column 3, Chiesi et al describes the type of acidic drugs used in the patent which is set forth to mean any drug having at least an acidic function such as a carboxy, sulfonic, sulfonylamino, sulfonylureic, phenol group and the

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like. Examples of classes of the acidic drugs disclosed by Chiesi et al comprises oxicams, hypoglycemic sulfonylureas, benzothiadiazine diuretics, barbituric acids, arylacetic and arylpropionic antiinflammatory acids. See column 6, lines 57 to 62 wherein Chiesi et al describes the information disclosed in Tables 1 and 4, which set forth the equilibrium solubility of some drugs used for the preparation of the complexes of the invention therein, wherein respective sodium salts and the physical mixture with β CD is used to determine the maximum solubility conditions at equilibrium. Also see Tables 2 and 4 wherein the instant solubility is determined for multicomponents Glibenclamide/ β CD/NaOH, Glibenclamide/ β CD/Diethanolamine, Piroxican/RAMEB/NaOH, and Piroxican/HP β CD /NaOH. The information set forth in Tables 1, 2 and 4 of the Chiesi et al patent allows for a comparison of the solubility properties of a series of salt, including salts of medicinal compounds as set forth in the instant claims and salts for use to make a composition of matter comprising an inclusion complex of a salt in a cyclodextrin as set forth in the instant claims.

The methods of determining a useful salt of the instant claims differ from methods of the Chiesi et al patent by claiming that the medicinal compound is ziprasidone.

The Matsumura et al publication shows that the use of cyclodextrin with phenyl-pieraziny compounds to increase the solubility of phenyl-pieraziny compounds is well known in the art. (See page 10, line 15 of the instant specification wherein it is stated that ziprasidone is set forth in U.S. Patent No. 4,831,031, wherein U.S. Pat. 4,831,031 discloses Arylpiperaziny-(ethyl or butyl)-heterocyclic compounds and their pharmaceutically acceptable salts. This patent is only cited show the chemical name for ziprasidone.) The Matsumura et al publication discloses easily soluble pharmaceutical compositions that comprises cyclodextrin, fluoro:phenyl-pieraziny-butyl di:hydro:di:benzo compounds (see title).

One of ordinary skill in this art would be motivated to combine the teachings of the Chiesi et al patent with the Matsumura et al publication since both references discloses medicinal compounds that are highly soluble when combined with cyclodextrin.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the medicinal compound used in the Chiesi et al patent to determine its cyclodextrin solubility with ziprasidone in view of the recognition in the art, as suggested by the Matsumura et al publication, that ziprasidone or phenyl-piperazinyl-butyl containing compounds with cyclodextrin are easily soluble pharmaceutical compositions.

Summary

5. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-066127. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



E. White



Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600